



DECLARATION OF CONFORMITY

Manufacturer:

Luropas del dottor Molinari & C. Srl
Via Vivaldi 4
24040 Calvenzano (BG) – Italy

We, the manufacturer, herewith declare that the following products:

ITEM CODE	PRODUCT NAME	INDED USE	DEVICE CLASS	CND CODES	BASIC UDI-DI
480	GAMBALETTO K1 – SIZE 2 GAMBALETTO K1 – SIZE 3 GAMBALETTO K1 – SIZE 4 GAMBALETTO K1 – SIZE 5	K1-K2-K3 medical hosiery, open toe. Indicated for venous pathologies with blood insufficiency, also chronic, development of varicose veins, phlebitis, oedema and varicose ulcers. Efficient in case of thrombophlebitis, postoperative prophylaxis, surgical operations on varicose veins, sclerotherapy and trauma and fractures of the lower limbs.	I, Rule 1 (Annex VIII of MDR2017/745)	M030405	803261520ULUOPAS7P
401	GAMBALETTO EXTRA K1 – SIZE 2 GAMBALETTO EXTRA K1 – SIZE 3 GAMBALETTO EXTRA K1 – SIZE 4 GAMBALETTO EXTRA K1 – SIZE 5 GAMBALETTO EXTRA K1 – SIZE 6			M030405	
402	CALZA COSCIA EXTRA K1 – SIZE 2 CALZA COSCIA EXTRA K1 – SIZE 3 CALZA COSCIA EXTRA K1 – SIZE 4 CALZA COSCIA EXTRA K1 – SIZE 5 CALZA COSCIA EXTRA K1 – SIZE 6 CALZA COSCIA EXTRA K1 – SIZE 7			M030405	
403	CALZA AUTOREGGENTE EXTRA K1 – SIZE 2 CALZA AUTOREGGENTE EXTRA K1 – SIZE 3 CALZA AUTOREGGENTE EXTRA K1 – SIZE 4 CALZA AUTOREGGENTE EXTRA K1 – SIZE 5			M030405	
406	COLLANT K1 CON APERTURA EXTRA – SIZE 2 COLLANT K1 CON APERTURA EXTRA – SIZE 3 COLLANT K1 CON APERTURA EXTRA – SIZE 4 COLLANT K1 CON APERTURA EXTRA – SIZE 5			M030405	
407	COLLANT CHIUSO EXTRA K1 – SIZE 2 COLLANT CHIUSO EXTRA K1 – SIZE 3 COLLANT CHIUSO EXTRA K1 – SIZE 4 COLLANT CHIUSO EXTRA K1 – SIZE 5			M030405	
408	MONOCOLLANT EXTRA K1 AMBIDESTRO – SIZE 2 MONOCOLLANT EXTRA K1 AMBIDESTRO – SIZE 3 MONOCOLLANT EXTRA K1 AMBIDESTRO – SIZE 4 MONOCOLLANT EXTRA K1 AMBIDESTRO – SIZE 5			M030405	
453	GAMBALETTO K2 – SIZE 2 GAMBALETTO K2 – SIZE 3 GAMBALETTO K2 – SIZE 4 GAMBALETTO K2 – SIZE 5			M030405	
455	AUTOREGGENTE K2 – SIZE 2 AUTOREGGENTE K2 – SIZE 3 AUTOREGGENTE K2 – SIZE 4 AUTOREGGENTE K2 – SIZE 5			M030405	
459	COLLANT SENZA APERTURA K2 – SIZE 2 COLLANT SENZA APERTURA K2 – SIZE 3 COLLANT SENZA APERTURA K2 – SIZE 4 COLLANT SENZA APERTURA K2 – SIZE 5			M030405	
409	MONOCOLLANT K2 AMBIDESTRO – SIZE 2 MONOCOLLANT K2 AMBIDESTRO – SIZE 3 MONOCOLLANT K2 AMBIDESTRO – SIZE 4 MONOCOLLANT K2 AMBIDESTRO – SIZE 5			M030405	
484	GAMBALETTO K3 MEDIO – SIZE 2 GAMBALETTO K3 MEDIO – SIZE 3 GAMBALETTO K3 MEDIO – SIZE 4			M030405	
485	GAMBALETTO K3 LUNGO – SIZE 2 GAMBALETTO K3 LUNGO – SIZE 3			M030405	

	GAMBALETTO K3 LUNGO – SIZE 4				
494	CALZA COSCIA K3 MEDIA– SIZE 2 CALZA COSCIA K3 MEDIA – SIZE 3 CALZA COSCIA K3 MEDIA– SIZE 4			M030405	
495	CALZA COSCIA K3 LUNGA – SIZE 2 CALZA COSCIA K3 LUNGA – SIZE 3 CALZA COSCIA K3 LUNGA – SIZE 4			M030405	
491	COLLANT K3 CON APERTURA MEDIO – SIZE 2 COLLANT K3 CON APERTURA MEDIO – SIZE 3 COLLANT K3 CON APERTURA MEDIO – SIZE 4			M030405	
464	COLLANT CHIUSO K3 MEDIO – SIZE 2 COLLANT CHIUSO K3 MEDIO – SIZE 3 COLLANT CHIUSO K3 MEDIO – SIZE 4			M030405	
410	MONOCOLLANT K3 AMBISISTRO MEDIO – SIZE 2 MONOCOLLANT K3 AMBISISTRO MEDIO – SIZE 3 MONOCOLLANT K3 AMBISISTRO MEDIO – SIZE 4			M030405	
411	MONOCOLLANT K3 AMBIDESTRO LUNGO – SIZE 2 MONOCOLLANT K3 AMBIDESTRO LUNGO – SIZE 3 MONOCOLLANT K3 AMBIDESTRO LUNGO – SIZE 4			M030405	

meet the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

Applicable standards:

UNI EN ISO 13485:2016
UNI CEI EN 15223-1:2017
ISO 14971:2019
ISO 10993-1: 2018
ISO 10993-5: 2018

We, the manufacturer, herewith declare under our own responsibility, that our above-mentioned products meet the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Natale Molinari

Stamp and signature

Date: 27/5/2021

Place: Calvenzano (BG), Italy

LUROPAS
del dott. Molinari & C. s.r.l.
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